

**IN THE UNITED STATES DISTRICT COURT  
FOR THE WESTERN DISTRICT OF PENNSYLVANIA**

**D.J.; TONI CORDOVA, *et al.***

**Plaintiffs,**

**v.**

**UNIVERSITY OF IOWA HOSPITALS  
AND CLINICS, *et al.*,**

**Defendants.**

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**Civil Action No. 2:22-cv-00752-CB**

**Judge Cathy Bissoon**

**DEFENDANTS' MEMORANDUM IN SUPPORT OF THEIR MOTION TO DISMISS**  
**PLAINTIFFS' COMPLAINT FOR LACK OF PERSONAL JURISDICTION**  
**AND**  
**PUBLIC ENTITY DEFENDANTS' MEMORANDUM IN SUPPORT OF THEIR**  
**MOTION TO DISMISS PLAINTIFFS' COMPLAINT FOR LACK OF SUBJECT**  
**MATTER JURISDICTION**

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Defendants University of Iowa Hospitals and Clinics, Dr. Ademola Abiose, Duke University Health System, Inc., Columbia University Medical Center, Dr. Maryam Banikazemi, Dr. Manesh Patel, Children’s Memorial Hospital (n/k/a Ann & Robert H. Lurie Children’s Hospital of Chicago), Dr. Joel Charrow, Baylor College of Medicine, Dr. Christine Eng, Cincinnati Children’s Hospital, Dr. Robert Hopkin, University of Minnesota, Dr. Michael Mauer, University of Washington Medicine, Dr. Ronald Scott, Massachusetts General Hospital, Dr. Katherine Sims, University of Alabama at Birmingham Medicine, Dr. David Warnock, Cedars-Sinai Medical Center, and Dr. William Wilcox (“Moving Defendants”), by and through undersigned counsel and pursuant to Federal Rule of Civil Procedure 12(b)(2), submit the following brief in support of their motion to dismiss Plaintiffs’ Complaint for lack of personal jurisdiction. Certain public entity Defendants and their respective physicians<sup>1</sup> also move to dismiss pursuant to either Federal Rule of Civil Procedure 12(b)(1) or 12(b)(2), and submit the following brief in support of their motion to dismiss Plaintiffs’ Complaint based on Eleventh Amendment immunity.

## **I. INTRODUCTION**

Plaintiffs bring this putative class action complaint against twenty-four defendants, none of whom are alleged to have any ties to the state of Pennsylvania. Compl. ¶¶ 17-40. Plaintiffs allege that Defendants, all out-of-state medical centers (“Medical Center Defendants”) or physicians (“Physician Defendants”), are responsible for harm Plaintiffs or their decedents allegedly sustained in connection with a shortage of a drug called Fabrazyme that began in 2009 and lasted until 2012. Plaintiffs or their decedents were prescribed Fabrazyme to manage symptoms

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<sup>1</sup> University of Iowa Hospitals and Clinics, Dr. Ademola Abiose, University of Minnesota, Dr. Michael Mauer, University of Washington Medicine, Dr. Ronald Scott, University of Alabama at Birmingham Medicine, and Dr. David Warnock.



of Fabry disease<sup>2</sup>, a rare genetic disorder where the body lacks an enzyme that breaks down a certain fat. *Id.* ¶¶ 1-16.

Plaintiffs admit Defendants “are not manufacturers or sellers of a drug.” *See id.* at p. 22. Instead, Sanofi Genzyme Corporation (“Genzyme”), which is not a party to this action, was the manufacturer of Fabrazyme. *Id.* ¶ 51-52, 55. Plaintiffs also admit they were not under the treatment or care of any Defendant. *Id.* ¶ 99. Instead, their theory of liability rests on claims that the Physician Defendants (and through the doctrine of respondeat superior, the Medical Center Defendants) violated Plaintiffs’ constitutional right to medical autonomy. Plaintiffs also contend Defendants conducted unauthorized or otherwise improper clinical research by participating in two meetings that resulted in two letters that were allegedly sent to all U.S. Fabry patients in 2009 that recommended adoption of Fabrazyme rationing plans to mitigate the effects of the drug shortage and asked patients to voluntarily report health data to a preexisting national registry. *Id.* ¶¶ 79-92, 100-118.

This is the fifth<sup>3</sup> lawsuit that counsel for Plaintiffs has filed in connection with the Fabrazyme shortage, and the first time Plaintiffs have asserted claims against this group of Defendants. Plaintiffs assert seven claims: (1) tort of failure to obtain informed consent; (2) breach of fiduciary duty; (3) violation of 42 U.S.C. § 1981 “Equal Protection under the Law”; (4) violation of 42 U.S.C. § 1983 “Protection of Rights from Those Acting Under Color of Law”; (5) violation of 42 U.S.C. § 1985(3) “Conspiracy to Deprive Rights from Citizens”; (6) violation of

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<sup>2</sup> <https://medlineplus.gov/genetics/condition/fabry-disease/>

<sup>3</sup> None of the four prior actions made it past the pleading stage. *See Hochendoner et al. v. Genzyme Corp., et al.*, Case No. 2:11-cv-00313-AJS (W.D. Pa.), transferred and later consolidated with *Adamo; Carik et al. v. Dept. of Health and Hum. Servs., et al.*, Case No. 1:12-cv-00272-BAH (D.D.C.); *Adamo et al. v. Genzyme Corp., et al.*, Case No. 1:13-cv-11336-DPW, (D. Mass.); *Wilkins et al. v. Sanofi Corp., et al.*, Case No. 4:20-cv-00051-TWP-DML (S.D. Ind.), transferred and re-styled as *Wilkins et al. v. Genzyme Corporation*, Case No. 1:21-cv-10023-DPW (D. Mass.).

42 U.S.C. § 1986 “Negligent Deprivation of Rights of Citizens”; and (7) violation of “Virginia Wrongful Death (Code of Virginia § 8.01-50) or in the alternative Survival Action Claims (Code of Virginia § 8.01-25).”<sup>4</sup> *Id.* ¶¶ 201-310. Plaintiffs bring these claims on behalf of a class defined as “any U.S. citizen that is or was a research subject of the effects of ‘low dose’ Fabrazyme (‘the Class’).” *Id.* ¶ 193.

Plaintiffs’ claims are subject to dismissal on various grounds, but are most easily dispensed with under Rule 12(b)(2), as the Court lacks personal jurisdiction over the Moving Defendants.<sup>5</sup> None of the Moving Defendants are at home in Pennsylvania, so the court lacks general jurisdiction over them. *See* Compl. ¶¶ 17-40. The Complaint also contains no plausible allegation that the Moving Defendants ever directed any activity to the state that could support the exercise of specific jurisdiction in this action. Plaintiffs allege there were two informational letters generated from meetings convened by Genzyme that were sent to “all Fabry patients in the U.S. including all of the named Plaintiffs.” *Id.* ¶¶ 83, 86. The Moving Defendants are identified as members of a Fabrazyme Stakeholder’s Working Group (“FSWG”) in those letters along with multiple individuals from Genzyme, but are not alleged to have drafted or sent the letters themselves. Regardless, Third Circuit authority provides that informational letters like these, and letters not targeted specifically at the forum state, do not support the exercise of personal jurisdiction. Even if such activity could support specific jurisdiction, the letters that resulted from the FSWG meetings did not give rise to the claims Plaintiffs assert in the

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<sup>4</sup> This claim is asserted by only Plaintiffs Eddie Viers, individually and as administrator of the Estate of Teresa Viers as substituted for Teresa Viers; Jeanne Wallace, individually and as administrator of the Estate Of Joseph Wallace as substituted for Joseph Wallace; James Wallace; and Samuel Wallace.

<sup>5</sup> With Court approval, the Moving Defendants address this issue first without waiving other Rule 12 arguments. Dkt. No. 69.

Complaint. As a result, all claims against the Moving Defendants should be dismissed for lack of personal jurisdiction.

Further, several Defendants are owned and operated by State public universities, which are arms of the State in which they are located (or are physicians at such institutions). The Eleventh Amendment precludes Plaintiffs' suit in this Court against those Defendants.<sup>6</sup> That immunity extends to all lawsuits where a State or State agency is a defendant, regardless of whether the claim is made under state or federal law (barring the application of limited exceptions, none of which apply here). Plaintiffs did not plead any facts that could lead this Court to conclude any Defendant waived its Eleventh Amendment protections. Accordingly, in addition to the lack of personal jurisdiction, all claims against the public entity Defendants and their current or former physicians must be dismissed pursuant to the Eleventh Amendment.

## II. STATEMENT OF RELEVANT FACTS

### A. Fabrazyme Shortage

Plaintiffs allege they or their decedent suffer(ed) from Fabry disease. Compl. ¶¶ 1-16. “Fabry (pronounced ‘fah-bray’) disease is a rare but lethal heritable genetic illness...” that presents from a “mutated or missing” gene responsible for making the alpha-galactosidase enzyme needed to metabolize globotriaosylceramide, also known as GL-3 fat. *Id.* ¶¶ 44, 46. Without this enzyme, GL-3 fat accumulates “in cells, blood vessels, and organs, which causes inflammation and ultimately leads to death, usually from strokes, kidney failure, and/or heart enlargement.” *Id.* ¶ 46.

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<sup>6</sup> With Court approval, the public entity Moving Defendants address this issue as well without waiving other Rule 12 arguments. Dkt. No. 69.

Fabrazyme, an “enzyme replacement therapy,” is the only FDA-approved drug for treating Fabry disease in the U.S. *Id.* ¶ 58. Plaintiffs allege that Fabrazyme “can be infused intravenously every two weeks to effectively treat Fabry patients.” *Id.* ¶ 47. Genzyme is the sole FDA-approved supplier of Fabrazyme. *Id.* ¶¶ 55, 57. Plaintiffs allege Genzyme contaminated its manufacturing facilities sometime before June 2009 and halted production of Fabrazyme in mid-June 2009 to sanitize the facility. *Id.* ¶¶ 63-64, Ex. A at 2. Genzyme halted production again in November 2009 because of manufacturing issues. *Id.* ¶ 65, Ex. B at 4. Plaintiffs assert these manufacturing shutdowns contributed to a Fabrazyme shortage that lasted two and a half years. *Id.* ¶¶ 64-66, 91.

**B. The Fabry Stakeholder’s Working Group**

Plaintiffs allege that on June 7, 2009, Genzyme convened a meeting of physicians who specialize in treating Fabry disease (called the Fabry Stakeholder’s Working Group, or “FSWG”) in Chicago, Illinois to determine how to address the Fabrazyme shortage. *Id.* ¶¶ 75, 79-81, 91, Ex. A at 2. The Physician Defendants all allegedly participated in the FSWG. *Id.* ¶ 81. Plaintiffs allege the FSWG resulted in an initial document titled: “Guidance to the Fabry Community on the Management of Fabrazyme (agalsidase beta) Supply.” *Id.* ¶ 83, Ex. A. The paper recommended that all patients reduce their Fabrazyme intake by the equivalent of two doses from July 1 to September 30, 2009, though it noted all treatment decisions would have to be made by individual patients’ treating physicians. *Id.* Ex. A. The paper stated the reduction could be achieved in one of two ways: either by skipping two full infusions or receiving a half-dose for four infusions. *Id.*

Plaintiffs allege Genzyme convened the FSWG a second time on September 23, 2009, after the Fabrazyme shortage continued longer than first expected. *Id.* ¶¶ 82, 85, Ex. B at 4.

This meeting resulted in a second paper titled: “Revised Guidance to the U.S. Fabry Community: Management of Fabrazyme (agalsidase beta for injection) Supply.” *Id.* ¶ 86, Ex. B. This revised guidance stated that Fabrazyme shipments would be reduced to 30% of expected demand until the end of 2009, and again noted all treatment decisions would still be made by individual patients’ treating physicians. *Id.* Ex. B. The paper recommended that patients spread their allotment of Fabrazyme over multiple infusions to minimize the time without treatment. *Id.* Plaintiffs allege these dose reductions lasted another two and one-half years until the spring of 2012. *Id.* ¶ 91.

Plaintiffs admit that the FSWG guidance documents “couched the [Fabrazyme dose reduction] recommendations as voluntary, stating that the decisions were up to the treating physicians.” *Id.* ¶ 90. Nevertheless Plaintiffs contend Defendants “knew that the dose reductions would be mandatory because [ ] Genzyme would adopt the FSWG recommended dose reductions when shipping Fabrazyme irrespective of the physician-patient treatment decision.” *Id.* Plaintiffs assert the “FSWG recommendations were . . . a mandate with the force of law so that American patients could not receive full doses and could not appeal the decision to accept ‘low doses’ to any governmental body.” *Id.* ¶ 147. In sum, Plaintiffs conclude that Defendants “assume[d] responsibility for managing the entire U.S. Fabrazyme supply by creating the autonomous FSWG” and “appointed themselves governmental public health authorities to manage the allocation of the Fabrazyme supply in all 50 U.S. states without taking into account individual medical conditions.” *Id.* ¶¶ 145, 148. Based on these allegations, Plaintiffs claim that “Defendants interfered with the Plaintiffs’ fundamental state and federal constitutional rights to medical autonomy by interfering with and countermanding U.S. Fabry Patients’ right to choose the individual medical treatment best for them.” *Id.* ¶ 260.

**C. The Fabry Registry Data**

Plaintiffs also contend Defendants failed to comply with various ethical and legal responsibilities for conducting human clinical trials. The revised guidance document resulting from the FSWG meeting in September 2009 “encouraged all U.S. doctors and patients to document the effects of ‘low dosing’ in a U.S. database termed ‘The Fabry Registry.’” *Id.* ¶ 93. The Fabry Registry, as Plaintiffs admit, is an observational longitudinal study for collecting data on Fabry disease where “[n]o experimental intervention is involved.” *Id.* ¶ 95. Plaintiffs allege they are all registered with the Fabry Registry, *id.* ¶¶ 1-16, but do not state whether they (or their treating physicians) ever reported any personal data to the Fabry Registry. Nor do Plaintiffs allege that any Defendant was involved in establishing the Fabry Registry.

Still, Plaintiffs claim that the FSWG engaged in “substantive human experimentation” by “[u]nilaterally lowering the dose of Fabrazyme while collecting data on the unknown effects.” *Id.* ¶ 97. Specifically, Plaintiffs allege Defendants did not obtain informed consent for this “study” and failed to warn patients that the lower doses of Fabrazyme “were likely ineffective and dangerous” once data was reported to the Fabry Registry. *Id.* ¶¶ 100-108. Plaintiffs also object to various papers and studies analyzing Fabry Registry data released in the years following the Fabrazyme shortage, vaguely alleging they use “methods of statistical manipulation” like “exclusion and averaging” to “conceal the American ‘low dose’ data.” *Id.* ¶ 174. Based on these allegedly misleading papers, Plaintiffs make a blanket accusation that all Physician Defendants are working to “actively conceal the effects of ‘low dose’” Fabrazyme. *Id.* ¶ 190.

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**D. The Moving Defendants**

The Complaint does not allege any Moving Defendant resides or is otherwise at home in Pennsylvania. It alleges the Physician Defendants reside in Ohio (Abiose), New York (Banikazemi), Illinois (Charrow), Texas (Eng), Ohio (Hopkin), Minnesota (Mauer), North Carolina (Patel), Washington (Scott), Massachusetts (Sims), Alabama (Warnock), and California (Wilcox)<sup>7</sup>. *Id.* ¶¶ 18, 20, 22, 24, 26, 28, 30, 32, 34, 36, 38. The Complaint alleges the Medical Center Defendants are incorporated and maintain principal places of business as follows:

<b>Complaint Paragraph</b>	<b>Medical Center Defendant</b>	<b>Place of Incorporation</b>	<b>Principal Place of Business</b>
¶ 17	University of Iowa Hospitals and Clinics	Iowa	Iowa City, Iowa
¶ 19	Columbia University Medical Center	New York	New York, New York
¶ 21	Children's Memorial Hospital	Illinois	Chicago, Illinois
¶ 23	Baylor College of Medicine	Texas	Houston, Texas
¶ 25	Cincinnati Children's Hospital Medical Center	Ohio	Cincinnati, Ohio
¶ 27	University of Minnesota Medical Center	Minnesota	Minneapolis, Minnesota
¶ 29	Duke University Health System, Inc.	North Carolina	Durham, North Carolina
¶ 31	University of Washington Medicine	Washington	Seattle, Washington
¶ 33	Massachusetts General Hospital	Massachusetts	Boston, Massachusetts
¶ 35	University of Alabama at Birmingham Medicine	Alabama	Birmingham, Alabama
¶ 37	Cedars-Sinai Medical Center	California	Los Angeles, California

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<sup>7</sup> Dr. William Wilcox was a California resident from 2009 to 2013 while he worked at Cedars-Sinai. Compl. ¶ 38; Ex. 1, Wilcox Decl. ¶ 3. Dr. Wilcox has been a Georgia resident since 2013. Ex. 1, Wilcox Decl. ¶ 4.

### III. STANDARD OF REVIEW

Defendants may move to dismiss for lack of personal jurisdiction under Federal Rule of Civil Procedure 12(b)(2). Plaintiff has the burden of pleading facts to support the court's personal jurisdiction over defendant. *Pinker v. Roche Holdings, Ltd.*, 292 F.3d 361, 368 (3d Cir. 2002) (citation omitted). Like a 12(b)(6) motion, the allegations related to personal jurisdiction are accepted as true. *Id.* When a defendant raises a challenge to personal jurisdiction, however, "the plaintiff must 'prove by affidavits or other competent evidence that jurisdiction is proper.'" *Metcalf v. Renaissance Marine, Inc.*, 566 F.3d 324, 330 (3d Cir. 2009) (citation omitted).

### IV. LACK OF PERSONAL JURISDICTION REQUIRES DISMISSAL

Plaintiffs assert federal subject matter jurisdiction based on both federal question and diversity jurisdiction. Compl. ¶ 41. Under diversity jurisdiction, personal jurisdiction over an out-of-state defendant is analyzed under the forum state's law. *Metcalf*, 566 F.3d at 330 (citation omitted). Under federal question jurisdiction, the limits of personal jurisdiction are analyzed under the Fifth Amendment's due process clause. *Weirbach v. Cellular Connection, LLC*, 478 F. Supp. 3d 544, 549 (E.D. Pa. 2020) (citing *Max Daetwyler Corp. v. A W. German Corp.*, 762 F.2d 290, 293 (3d Cir. 1985)). That said, when a plaintiff asserts a claim under a federal law that does not provide for nationwide service of process, the court may exercise personal jurisdiction only "to the extent [the defendant] is 'subject to the jurisdiction' of [the forum state's] courts." *Fischer v. Fed. Express Corp.*, 42 F.4th 366, 382 (3d Cir. July 26, 2022) (quoting Fed. R. Civ. P. 4(k)(1)(A)).

#### A. No Federal Statute Authorizes Nationwide Service of Process for These Claims

There is no federal statute that authorizes nationwide service of process for Plaintiffs' claims. *Stifel v. Lindhorst*, 393 F. Supp. 1085, 1087 (M.D. Pa. 1975) ("Neither [28 U.S.C.] §



1332 nor § 1343 provide for Nationwide service of process.”); *Echlinaw v. Lappin*, No. 08-3011-KHV, 2009 U.S. Dist. LEXIS 17842, \*24 (D. Kan. Mar. 9, 2009) (same for 28 U.S.C. § 1331); *Scott v. Kerry*, No. 15-5983, 2016 U.S. Dist. LEXIS 164873, \*3-4, 7-10 (E.D. Pa. Nov. 30, 2016) (analyzing claims under 42 U.S.C. § 1981 and § 1985 and finding no nationwide service of process); *Canuto v. Maattis*, 273 F. Supp. 3d 127, 138 n.14 (D.D.C. 2017) (noting 42 U.S.C. § 1981 and § 1983 do not authorize nationwide service of process); *K.O. v. Sessions*, 436 F. Supp. 3d 442, 448 (D. Mass. 2020) (same for 42 U.S.C. § 1985 or § 1986). Accordingly, whether analyzing personal jurisdiction under federal question or diversity, this Court should look to Pennsylvania’s long-arm statute to determine whether it has personal jurisdiction over the defendants in this case. *Max Daetwyler Corp.*, 762 F.2d at 297; *see* Fed. R. Civ. P. 4(e), (k).

**B. Pennsylvania’s Long Arm Statute Requires Sufficient Minimum Contacts with Pennsylvania that Are Lacking Here**

The Pennsylvania long-arm statute provides for the exercise of personal jurisdiction consistent with the Fourteenth Amendment’s due process clause. *Weirbach*, 478 F. Supp. 3d at 550 (citing 42 Pa. C.S.A. § 5322(b)). Due Process requires minimum contacts with Pennsylvania such that exercising personal jurisdiction ““does not offend traditional notions of fair play and substantial justice.”” *O’Connor v. Sandy Lane Hotel Co.*, 496 F.3d 312, 316-17 (3d Cir. 2007) (citing *Int’l Shoe Co. v. Washington*, 326 U.S. 310, 316 (1945)). “In evaluating whether personal jurisdiction exists, the Court may only consider the actions taken by the defendant individually.” *Nationwide Contr. Audit Serv. v. Nat’l Compliance Mgmt. Servs.*, 622 F. Supp. 2d 276, 283 (W.D. Pa. 2008) (citing *Helicopteros Nacionales de Colombia, S.A. v. Hall*, 466 U.S. 408, 417 (1984))).

Personal jurisdiction can be general or specific. *O’Connor*, 496 F.3d at 317 (citing *Helicopteros*, 466 U.S. at 414-15). General jurisdiction is exercised in a person’s domicile

which for a corporation includes “its place of incorporation and principal place of business.” *Ford Motor Co. v. Mont. Eighth Jud. Dist. Court*, 141 S. Ct. 1017, 1024 (2021) (citation omitted) (noting the possibility remains of a corporation being found “at home” somewhere else under only exceptional circumstances). For a court to exercise specific jurisdiction, the case ““must arise out of or relate to the defendant’s contacts’ with the forum.” *Ford Motor Co.*, 141 S. Ct. at 1025 (citations omitted).

The Third Circuit applies the following three-part test when analyzing specific jurisdiction: (1) “the defendant must have ‘purposefully directed its activities’ at the forum”; (2) “the litigation must ‘arise out of or relate to’ at least one of those activities”; and (3) does “the exercise of jurisdiction otherwise ‘comport[] with fair play and substantial justice.’” *O’Connor*, 496 F.3d at 317 (citations omitted). The specific jurisdiction analysis is generally “on a claim by claim basis.” *Marten v. Goodwin*, 499 F.3d 290, 296 (3d Cir. 2007) (citation omitted).

The Third Circuit also recognizes an “effects test” based on *Calder v. Jones*, 465 U.S. 783 (1984) which can establish specific jurisdiction for intentional torts. *Marten*, 499 F.3d at 297. The three parts of this test are:

- (1) The defendant committed an intentional tort; (2) The plaintiff felt the brunt of the harm in the forum such that the forum can be said to be the focal of the harm suffered by the plaintiff as a result of that tort; (3) The defendant expressly aimed his tortious conduct at the forum such that the forum can be said to be the focal point of the tortious activity.

*Marten*, 499 F.3d at 297 (citation omitted). The third prong requires more than the defendant knowing the plaintiff resides in the state because this “would render the requirements of personal jurisdiction illusory as every plaintiff suffers harm in the state where he or she resides.” *Nationwide Contr. Audi Serv. v. Nat’l Compliance Mgmt. Servs.*, 622 F. Supp. 2d 276, 298-99 (W.D. Pa. 2008) (citations omitted).

**C. This Court cannot assert general jurisdiction over Defendants because Defendants are not at home in Pennsylvania**

Plaintiffs allege no facts to support the application of general jurisdiction over any of the Moving Defendants. As explained above (Part II.D), none of the Physicians Defendants are residents of Pennsylvania. None of the Medical Center Defendants are incorporated in Pennsylvania and they all maintain principal places of business in other states. Thus, the Court cannot exercise general jurisdiction over the Moving Defendants. *See, e.g., Daimler AG v. Bauman*, 571 U.S. 117, 139 (2014).

**D. This Court does not have specific jurisdiction over Defendants because this action does not rise out of any contacts Defendants had with the forum**

Second, Plaintiffs cannot establish specific jurisdiction over the Moving Defendants because they do not allege any in-state conduct by any Moving Defendant gave rise to Plaintiffs' claims. The only contact with Pennsylvania that Plaintiffs allege was the provision (via unidentified channels) of the two FSWG letters to all Fabry patients in the U.S., some of whom live in Pennsylvania. Compl. ¶¶ 42-43, 83, 86. To be clear, the Complaint does not allege any of the Moving Defendants caused these documents to be sent to Pennsylvania. Even if it did, such activity does not give rise to specific jurisdiction under the minimum contacts test. "[The Third Circuit] has recognized that 'informational communications in furtherance of a contract between a resident and a nonresident does not establish the purposeful activity necessary for a valid assertion of personal jurisdiction over the nonresident defendant'" under the minimum contacts analysis. *Vetrotex Certainteed Corp. v. Consolidated Fiber Glass Prods. Co.*, 75 F.3d 147, 152-54 (3d Cir. 1996) (citations omitted). Further, the "'minimum contacts' analysis looks to the defendant's contacts with the forum State itself, *not the defendant's contacts with persons who reside there.*" *Walden v. Fiore*, 571 U.S. 277, 285 (2014) (emphasis added). "[T]he plaintiff cannot be the only link between the defendant and the forum." *Id.* "Rather, it is the

defendant's conduct that must form the necessary connection with the forum State that is the basis for its jurisdiction over him." *Id.* Plaintiffs here fail to allege any such conduct of the Defendants connected with the state of Pennsylvania.

In any event, Plaintiffs' claims do not arise from the *provision* of the FSWG letters to Fabry patients. Plaintiffs claim the Moving Defendants violated their constitutional right to medical autonomy when the FSWG *issued* the guidance in the first place, not when informational letters were later sent informing patients of that guidance. All of Plaintiffs' claims flow from the alleged dosing modification recommendation made to or developed with Genzyme in light of the shortage, not the subsequent communication of that recommendation to patients. That individuals with Fabry received an informational letter informing them that this recommendation had been made was not the source of any injury Plaintiffs allege.

Plaintiffs cannot satisfy the effects test either. In analyzing personal jurisdiction under the effects test in *Nationwide*, the court noted sending out hundreds of postcards "to Operators and Contractors through the United States, not only Pennsylvania," did not support a finding of tortious conduct aimed at Pennsylvania. *Nationwide*, 622 F. Supp. 2d at 301. The Third Circuit likewise found a letter sent to a Pennsylvania plaintiff's office that was seen by two people in the office and a second letter published in the boxing community about the plaintiff did not satisfy personal jurisdiction under the effects test for a defamation claim because there was no showing the letters were aimed at Pennsylvania or "that Pennsylvania has a unique relationship with the boxing industry." *Remick v. Manfredy*, 238 F.3d 248, 257-59 (3d Cir. 2001). And again, the Complaint does not allege that the provision of the FSWG letters to all Fabry patients in the U.S. is tortious conduct.

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Pennsylvania does not have a unique relationship with Fabry patients, who are located throughout the United States and elsewhere. Compl. ¶¶ 51, 72. The letters thus cannot be considered to be targeted at Pennsylvania. *Nationwide*, 622 F. Supp. 2d at 301; *Remick*, 238 F.3d at 259; *Vetrotext Certainteed Corp.*, 75 F.3d at 152. The letters were informational with suggestions of how doctors and patients should respond to a drug shortage. Compl. Exs. A, B. This cannot establish that the Moving Defendants purposefully availed themselves of the privilege of doing business in Pennsylvania through these letters. *See M.S. Western Power Sports, Inc.*, 512 F. Supp. 3d 604, 608 (W.D. Pa. 2021) (finding defendant shipping product to plaintiff's warehouse in Pennsylvania only showed an attempt "'to exploit a national market,' as opposed to the 'deliberate targeting of the forum' the Third Circuit requires to support specific personal jurisdiction"). Indeed, Plaintiffs allege the letters directed people to contact the drug manufacturer, not members of the FSWG or their affiliated institutions which shows the Moving Defendants were not attempting to do business. Compl. ¶ 111.

In sum, Plaintiffs have no evidence that any of the Moving Defendants have directed activity to Pennsylvania on which Plaintiffs' claims are based. By way of example, Defendants Cedars-Sinai, Dr. Wilcox, and Dr. Sims submit declarations stating the following facts:

- None reside in Pennsylvania.
- Cedars-Sinai is incorporated in and has its principal place of business in California.
- Dr. Wilcox previously resided in California, currently resides in Georgia, and has never resided in Pennsylvania.
- Dr. Sims resides in Massachusetts and has never resided in Pennsylvania.
- None has or ever had offices in Pennsylvania.
- None have a bank account in Pennsylvania.
- None are licensed to practice medicine in Pennsylvania.
- None have ever treated patients in Pennsylvania.
- None of the named Plaintiffs were patients of Cedars-Sinai, Dr. Wilcox, or Dr. Sims.

- None direct advertising or marketing at Pennsylvania.
- None have an authorized agent to receive service of process in Pennsylvania.
- None own land in Pennsylvania.
- None has a mailing address or telephone or fax listing in Pennsylvania.
- None drafted either of the FSWG Guidance letters
- None mailed either of the FSWG Guidance letters to anyone, including patients or doctors in Pennsylvania.
- None approved the mailing of either of the FSWG Guidance letters to patients in Pennsylvania or anywhere.
- The two FSWG meetings referenced in the Complaint did not take place in Pennsylvania.

Ex 2, Wrigley Decl. ¶¶ 1-12; Ex 1, Wilcox Decl. ¶¶ 1-19; Ex. 3, Sims Decl. ¶¶ 1-19.

Plaintiffs admit no Defendant treated any named Plaintiff, which necessarily includes the two named Plaintiffs that reside in Pennsylvania. Compl. ¶¶ 42-43, 99. While Plaintiffs allege the FSWG met twice, the first meeting allegedly occurred in Chicago, Illinois, not Pennsylvania, and the second meeting location is not alleged. *Id.* ¶ 82. It was not in Pennsylvania. Ex. 1, Wilcox Decl., ¶ 19; Ex. 3, Sims Decl. ¶ 19. There is nothing to show hailing the Moving Defendants into court in Pennsylvania would be fair or reasonable and consistent with federal due process standards for exercising personal jurisdiction. Such a showing is also not possible. All Moving Defendants should be dismissed from this case for lack of personal jurisdiction.

**V. THE STATE ENTITY DEFENDANTS AND THEIR PHYSICIANS ARE IMMUNE FROM SUIT IN FEDERAL COURT UNDER THE ELEVENTH AMENDMENT<sup>8</sup>**

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<sup>8</sup> The Third Circuit appears to consider Eleventh Amendment immunity as a jurisdictional bar depriving the Court of subject matter jurisdiction. *See, e.g., Christ the King Manor, Inc. v. Sec’y U.S. Dep’t of Health & Hum. Servs.*, 730 F.3d 291, 318 (3d Cir. 2013). That said, the Third Circuit has also recognized that “the Supreme Court’s jurisprudence has not been entirely consistent in the view that the Eleventh Amendment restricts subject matter jurisdiction.” *Lombardo v. Pennsylvania, Dep’t of Pub. Welfare*, 540 F.3d 190, 197 n.6 (3d Cir. 2008). Some aspects of the doctrine more closely mirror personal jurisdiction. *Id.* Irrespective of the

Because this Court should dismiss this case in its entirety based on the lack of personal jurisdiction, this Court need not reach this Eleventh Amendment issue. In the event the Court finds that it has personal jurisdiction, however, the Eleventh Amendment precludes all claims asserted against the public entity Defendants<sup>9</sup> and their respective physicians.<sup>10</sup>

“The Eleventh Amendment ‘bar[s] all private suits against non-consenting States in federal court,’ *Lombardo v. Pa., Dep’t of Pub. Welfare*, 540 F.3d 190, 194 (3d Cir. 2008), with the goal of protecting ‘the States’ solvency and dignity,’ *Hess v. Port Auth. Trans-Hudson Corp.*, 513 U.S. 30, 52 (1994).” *Allen v. New Jersey State Police*, 974 F.3d 497, 504 (3d Cir. 2020).<sup>11</sup> “The Amendment ‘has been interpreted by the Supreme Court to shield States and certain State-affiliated entities from suits for damages in federal court.’” *Id.* (quoting *Bradley v. W. Chester Univ. of Pa. State Sys. of Higher Educ.*, 880 F.3d 643, 654 (3d Cir. 2018)). “There is no

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doctrinal framework this Court uses, the Eleventh Amendment is a jurisdictional bar in this case to all claims against the public entity Defendants and their physicians.

<sup>9</sup> The public entity Defendants are identified *supra*, at note 1.

<sup>10</sup> To be clear, this section discusses *only* the relevant States’ Eleventh Amendment immunity, and *not* their separate entitlement to state sovereign immunity. The Supreme Court has recognized “that ‘the Eleventh Amendment does not define the scope of the States’ sovereign immunity; it is but one particular exemplification of that immunity.’” *Lombardo*, 540 F.3d at 195 (quoting *Fed. Mar. Comm’n v. S.C. State Ports Auth.*, 535 U.S. 743, 753 (2002)). “Consequently, ‘the sovereign immunity enjoyed by the States extends beyond the literal text of the Eleventh Amendment,’” and “comprises more than just immunity from suit in federal court.” *Id.* (quoting *Alden v. Maine*, 527 U.S. 706, 713 (1999)).

Each State’s own sovereign immunity, of course, is a unique creature of state law, and each State’s sovereign immunity doctrine is therefore not discussed in this omnibus brief. But each public entity Defendant and their respective physicians expressly reserve the right to assert their own sovereign immunities, which provide yet another barrier to Plaintiffs’ claims.

<sup>11</sup> See also, e.g., *Edelman v. Jordan*, 415 U.S. 651, 662, 94 S. Ct. 1347, 1355, 39 L. Ed. 2d 662 (1974); *Employees v. Department of Pub. Health and Welfare*, 411 U.S. 279, 93 S.Ct. 1614, 36 L.Ed.2d 251 (1973); *Great Northern Life Insurance Co. v. Read*, 322 U.S. 47, 64 S.Ct. 873, 88 L.Ed. 1121 (1944); *Duhne v. New Jersey*, 251 U.S. 311, 40 S.Ct. 154, 64 L.Ed 280 (1920); *Hans v. Louisiana*, 134 U.S. 1, 15, 10 S. Ct. 504, 507, 33 L. Ed. 842 (1890).

exception to Eleventh Amendment immunity for plaintiffs who bring state law claims against a state.” *Id.* (citing *Pennhurst State Sch. & Hosp. v. Halderman*, 465 U.S. 89, 106 (1984)).

Agencies and other state groups may claim protection under the Eleventh Amendment if they qualify as “arms of the state.” “[C]omity and state sovereignty are constitutional precepts and lynchpins of our federalist system of government, and where, as here, the State creates an entity that functions on balance as an arm of the State, the Eleventh Amendment's protection must carry the day.” *Maliandi v. Montclair State Univ.*, 845 F.3d 77, 99 (3d Cir. 2016).

The Third Circuit has consistently held state universities to be arms of the state. *Bowers v. NCAA*, 475 F.3d 524, 549 (3d Cir. 2007) (“the overwhelming degree of state involvement in the University of Iowa warrants a finding that the University is an arm of the state.”); *Nannay v. Rowan Coll.*, 101 F. Supp. 2d 272, 284 (D.N.J. 2000) (“applying the *Fitchik* test in this case leads to a conclusion that Rowan is entitled to Eleventh Amendment immunity”); *Bradley v. W. Chester Univ. of Pennsylvania State Sys. of Higher Educ.*, 880 F.3d 643, 660 (3d Cir. 2018) (“after weighing and balancing the qualitative strength of each factor in the context of the circumstances presented we hold that those institutions are entitled to Eleventh Amendment immunity”); *Maliandi*, 845 F.3d at 99 (“where ... the State creates an entity that functions on the balance as an arm of the State, the Eleventh Amendment’s protection must carry the day”).

Moreover, courts in the public entity Defendants’ respective jurisdictions have likewise held them to be arms of the state for purposes of the Eleventh Amendment. *See, e.g., Does 1-2 v. Regents of the Univ. of Minnesota*, 999 F.3d 571, 583 (8th Cir. 2021) (University of Minnesota); *Brine v. Univ. of Iowa*, 90 F.3d 271, 275 (8th Cir. 1996) (University of Iowa); *Page v. Hicks*, 773 F. App’x 514, 518 (11th Cir. 2019) (University of Alabama at Birmingham); *Goodisman v. Lyle*, 724 F.2d 818, 820 (9th Cir. 1984) (implying that the University of Washington is an arm of the



state, and holding that plaintiff is barred under the Eleventh Amendment from seeking money damages from the state treasury through liability of University officials in their official capacities).

**A. The Eleventh Amendment also bars claims against the public entity Defendants’ respective physicians**

In addition to the entities themselves, “a suit brought against an individual acting in his or her official capacity is deemed to be a suit against the state and, therefore, also is barred by the Eleventh Amendment.” *O’Donnell v. Pennsylvania Dep’t of Corr.*, 790 F. Supp. 2d 289, 305 (M.D. Pa. 2011) (citing *Will v. Michigan Dep’t of State Police*, 491 U.S. 58, 71 (1989)), *aff’d*, 507 Fed. Appx. 123 (3d Cir. 2012). “Pursuant to the Eleventh Amendment, states, state agencies and state officials who are sued in their official capacity are generally immune from lawsuits in federal courts brought against them by citizens.” *Id.*

Where, as here, a complaint is silent as to whether individuals are sued in their official or individual capacities, the Third Circuit requires this Court “to ‘interpret the pleading’ instead of applying a strict rule presuming one capacity or the other.” *Dunn v. Tunkhannock Twp.*, 2021 WL 1122994, at \*7 n.10 (M.D. Pa. Mar. 24, 2021) (quoting *Melo v. Hafer*, 912 F.2d 628, 636 & n.7 (3d Cir. 1990)). Plaintiffs never assert that any of the Physician Defendants were acting outside their official capacities, nor do they allege that they are suing the Physician Defendants in anything other than their official capacity. To the contrary, Plaintiffs specifically allege that these Physician Defendants were “representing their respective medical institutions” at all material times. *See* Compl. at 27-28, ¶ 81. Accordingly, all claims against each of the Physician Defendants working for State entities<sup>12</sup> are also barred by the Eleventh Amendment.

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<sup>12</sup> This includes Dr. Ademola Abiose; Dr. Michael Mauer; Dr. Ronald Scott; and Dr. David Warnock.

**B. The public entity Defendants and their physicians are immune from suit under the Eleventh Amendment from Plaintiffs’ asserted claims**

Because Eleventh Amendment immunity protects both the public entity Defendants and their physicians, all that remains is to apply the Eleventh Amendment to the specific claims asserted by Plaintiffs. A state may waive its Eleventh Amendment immunity in one of only two ways: (1) the State invokes federal jurisdiction by bringing the suit itself; or (2) if the state has made a “clear declaration” of intent to be subjected to the jurisdiction of federal courts. *Allen v. New Jersey State Police*, 974 F.3d 497, 505 (3d Cir. 2020); *see also Coll. Sav. Bank v. Florida Prepaid Postsecondary Educ. Expense Bd.*, 527 U.S. 666, 675 (1999). “Waiver of Eleventh Amendment immunity will be found ‘only where the state’s consent is stated by the most express language or by such overwhelming implications from the text as [will] leave no room for any other reasonable construction.’” *Allen*, 974 F.3d at 505 (quoting *M.A. ex rel. E.S. v. State-Operated Sch. Dist. of City of Newark*, 344 F.3d 335, 345 (3d Cir. 2003)). Additionally, with respect to federal statutes, Congress may abrogate the States’ Eleventh Amendment immunity, but, in order to do so, “Congress ‘must express its intention to abrogate the Eleventh Amendment in unmistakable language in the statute itself.’” *Blanciak v. Allegheny Ludlum Corp.*, 77 F.3d 690, 694 (3d Cir. 1996) (quoting *Atascadero State Hospital v. Scanlon*, 473 U.S. 234, 242 (1985)).

Here, Plaintiffs assert state-law claims (Counts 1, 2, and 7), as well as federal claims (Counts 3 through 6). With respect to Plaintiffs’ state-law claims, the analysis is very straightforward, because neither of the two bases for “waiver” of Eleventh Amendment immunity are remotely applicable. First, the public entity Defendants of course did not invoke federal jurisdiction, because they did not file this action. Second, Plaintiffs have pled no facts in their Complaint that any of the public entity Defendants have waived their Eleventh Amendment

immunity. Moreover, case law from each represented jurisdiction confirms that none of the relevant states have waived their Eleventh Amendment immunity.<sup>13</sup> Thus, because none of the states have waived their Eleventh Amendment immunity—and because “[t]here is no exception to Eleventh Amendment immunity for plaintiffs who bring state law claims against a state,” *Allen*, 974 F.3d at 505—Counts 1, 2, and 7 are barred against the public entity Defendants and their physicians.

Plaintiffs fare no better on their federal claims. For the same reasons as discussed on the state-law claims, there is no waiver of Eleventh Amendment immunity. Additionally, for Plaintiffs’ primary federal claim—the § 1983 claim—it is black-letter law that Congress did not abrogate the States’ Eleventh Amendment immunity when passing § 1983. *See e.g., Alston v. Kean Univ.*, 549 F. App’x 86, 89 (3d Cir. 2013) (citing *Quern v. Jordan*, 440 U.S. 332, 340-41 (1979)). “Similarly, the states’ immunity has not been abrogated for actions brought under §§ 1981, 1985, and 1986.” *Boykin v. Bloomsburg Univ. of Pennsylvania*, 893 F. Supp. 378, 394 (M.D. Pa. 1995), *aff’d*, 91 F.3d 122 (3d Cir. 1996). Accordingly, for each of the four statutes upon which Plaintiffs base their federal claims--§§ 1981,<sup>14</sup> 1983, 1985, and 1986—case law confirms Congress has not abrogated the States’ Eleventh Amendment immunity, which therefore bars Counts 3 through 6 against the public entity Defendants and their physicians.<sup>15</sup>

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<sup>13</sup> *Hageman v. Minnesota Dep’t of Corr.*, No. 21-2096 (JRT/BRT), 2022 WL 4396465, at \*3 (D. Minn. Sep. 23, 2022) (“Minnesota has not waived its Eleventh Amendment immunity from suit in federal court.”); *Flugge v. Hollenbeck*, No. C16-2121-LTS, 2017 WL 2640674, at \*3 (N.D. Iowa June 19, 2017) (noting that Iowa federal courts have consistently held that the Iowa Tort Claims Act does not contain a waiver of Eleventh Amendment immunity); *Amiri v. Bd. of Trustees of Univ. of Ala.*, 440 F. Supp. 3d 1267, 1273-74 (N.D. Ala. 2020) (federal courts have “repeatedly found that Alabama has not waived its Eleventh Amendment immunity.”).

<sup>14</sup> To be clear, § 1981 contains no private right of action, so Count III will never be actionable. *See, e.g., McGovern v. City of Philadelphia*, 554 F.3d 114, 116 (3d Cir. 2009).

<sup>15</sup> Relatedly, “‘States or governmental entities that are considered “arms of the State” for Eleventh Amendment purposes’ are not ‘persons’ under § 1983,” and the claim fails at the outset

Pursuant to the Eleventh Amendment, this Court should dismiss all of Plaintiffs' claims against the public entity Defendants and their respective physicians.

## VI. CONCLUSION

The Moving Defendants respectfully request the Court dismiss them from this action for lack of personal jurisdiction without granting Plaintiffs leave to amend. The public entity Defendants additionally request the Court dismiss them and their current or former physicians from this action pursuant to the Eleventh Amendment.

*[signatures on following page]*

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for this reason as well. *Karns v. Shanahan*, 879 F.3d 504, 519 (3d Cir. 2018) (quoting *Will*, 491 U.S. at 70). The Third Circuit has “emphasize[d] that the Eleventh Amendment and § 1983 determinations are ‘analytically distinct,’ although sometimes overlapping. *Id.* at 519 n.6 (citations omitted). “Where, as here, the entity claiming immunity is determined to be an arm of the state, however, it is beyond dispute that it is not a ‘person’ for § 1983 purposes.” *Id.* Moreover, “the term ‘persons’ in section 1983 has the same meaning under sections 1985 and 1986.” *New Jersey Chinese Cmty. Ctr. v. McAleer*, No. 21-08320 (FLW), 2022 WL 3403297, at \*7 (D.N.J. Aug. 15, 2022).

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